

EXHIBIT 1

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Attorneys for Plaintiff

CENTOCOR ORTHO BIOTECH, INC.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

CENTOCOR ORTHO BIOTECH,
INC.,

Plaintiffs,

v.

GENENTECH, INC. and CITY OF
HOPE NATIONAL MEDICAL
CENTER,

Defendants.

Case No. CV 08-03573 MRP (CTx)

Hon. Mariana R. Pfaelzer

**SUPPLEMENTAL RESPONSES TO
GENENTECH'S
INTERROGATORIES NOS. 16 & 17**

Pursuant to Federal Rule of Civil Procedure 26 and 33, Plaintiff Centocor Ortho Biotech, Inc. ("Centocor") hereby supplements its responses and makes the following objections to Interrogatories Nos. 16 & 17 of Genentech, Inc. ("Genentech") as follows:

GENERAL STATEMENT

1. Centocor's responses are made without in any way waiving or intending to waive, but to the contrary, intending to preserve and preserving:

a. The right to raise all questions of authenticity, relevancy, materiality, privilege and admissibility as evidence for any purpose of the information provided and the documents identified and/or produced in response to these interrogatories, which may arise in any subsequent proceeding in, or the trial of, this or any other action;

b. The right to object to the use of the information and/or documents in any subsequent proceeding in, or the trial of, this or any action on any grounds;

c. The right to object on any ground at any time to other interrogatories or other discovery involving the information and/or documents or the subject matter thereof; and

d. The right to make subsequent answers if Centocor uncovers additional information and/or documents called for by these interrogatories since Centocor's investigation of the facts and the evidence pertinent to this action has not been completed.

2. Words and terms used in the following responses shall be construed in accordance with their normal meanings or connotations, and shall in no way be interpreted as terms of art or statutorily defined terms used in the patent laws.

GENERAL OBJECTIONS

1. Centocor objects to the "Definitions" to the Interrogatories to the extent they impose, or attempt to impose, obligations and demands beyond those contemplated by Rules 26 and 33 of the Federal Rules of Civil Procedure.

2. Centocor objects to the Interrogatories to the extent that they seek, or may be construed to seek, information immune from discovery by reason of the attorney-client privilege, the work product immunity, and/or the protections afforded by Rule 26(b)(4)(B). The specific objections stated below on the grounds of attorney-client privilege, work product, and/or Rule 26(b)(4)(B) in no way limit the generality of this objection. Nothing contained in these responses is intended to be nor should be considered a waiver of any attorney-client privilege, work product immunity, Rule 26(b)(4)(B) protection, or any other applicable privilege or doctrine, and to the extent that any interrogatory may be construed as calling for disclosure of information or documents protected by such privileges or immunities,

1 a continuing objection to each and every such interrogatory is hereby imposed.
2 Any inadvertent release of such information shall not constitute a waiver of any
3 applicable privilege or protection.

4 3. At this time, Centocor objects to providing the requested information
5 concerning any documents or things withheld on the basis of attorney-client or
6 work product immunity. Centocor will prepare a privilege log for exchange at a
7 time mutually agreed upon by the parties.

8 4. Centocor objects to each interrogatory, definition, or instruction to the
9 extent it purports to seek or require Centocor to provide information that is not
10 within Centocor's possession, custody, or control or to the extent it purports to
11 require Centocor to identify documents not presently within Centocor's
12 possession, custody, or control. Centocor also objects to each interrogatory to the extent
13 that it seeks information that is already in the possession, custody or control of
14 Genentech or Genentech's counsel.

15 5. All responses to Genentech's interrogatories are supplied by Centocor
16 subject to all objections as to competence, relevance, materiality, propriety,
17 admissibility and any and all other objections on any grounds that would require
18 the exclusion of the response or information if such were offered in evidence, all of
19 which objections and grounds are hereby expressly reserved and may be interposed
20 at the time of trial.

21 6. Except as otherwise stated herein, Centocor objects to each
22 interrogatory, definition, or instruction as vague, overbroad, unduly burdensome,
23 and oppressive, to the extent it seeks information that is neither relevant to the
24 parties' claims or defenses in this action nor reasonably calculated to lead to the
25 discovery of admissible evidence.

26 7. Centocor objects to the definition of "Plaintiff," "Counter-Defendant,"
27 "Centocor," "You," and "Your" to the extent that, by incorporating such definition,
28 the interrogatories demand discovery of persons or entities other than Centocor and
those within its direct control. Centocor also objects to all of the subject
interrogatories as overly broad and unduly burdensome to the extent they demand
discovery of any of foreign subsidiaries or entities.

8. Centocor objects to the definition of "CENTOCOR ANTIBODY
PRODUCTS" in paragraph 10 of the "Definitions" and to each of Genentech's
individual interrogatories that use that term as overly broad, unduly burdensome,
and not reasonably calculated to lead to the discovery of admissible evidence.
Centocor will respond to individual interrogatories that use the term "CENTOCOR
ANTIBODY PRODUCTS" as limited to and referring to the products accused by
defendants, *i.e.* ReoPro®, Remicade®, CNTO 1275, and CNTO 148, unless
otherwise stated.

9. Centocor objects to each interrogatory to the extent that it uses
language incorporating or calling for a legal conclusion or making an erroneous

statement of law. Centocor's responses herein shall be as to matters of fact only, and shall not be construed as stating or implying any conclusions of law concerning the matters referenced in any interrogatory.

10. Centocor objects to each definition, instruction, and interrogatory to the extent it requires any information or documents beyond what is presently available to Centocor based upon a reasonable search of its own files and a reasonable inquiry of its present employees. Centocor's responses herein are based on facts presently known to it and represent a diligent and good faith effort to comply. Centocor's discovery and investigation into the matters specified is continuing. Accordingly, Centocor reserves its right to supplement, alter or change its responses and objections to the interrogatories and to produce additional responsive information and/or documents. Furthermore, Centocor reserves the right, at trial or during other proceedings in this action, to rely on documents, evidence, and other matters in addition to the documents and/or information produced in response to interrogatories, whether or not such documents, evidence, or other matters are newly discovered or are now in existence but have not been located despite diligent and good faith efforts.

11. The applicable foregoing general objections are incorporated into each of the specific objections and responses that follow. The stating of a specific objection or response shall not be construed as a waiver of Centocor's general objections.

12. Centocor expressly reserves the right to supplement these General Objections.

INTERROGATORIES

INTERROGATORY NO. 16

Provide a complete statement of each and every basis for YOUR contention(s) that the '415 PATENT is unenforceable due to inequitable conduct, including but not limited to, all information that supports or rebuts YOUR contention(s), and identification of all PERSONS most knowledgeable of and DOCUMENTS RELATING TO YOUR contention(s). If YOU contend that the '415 PATENT is unenforceable due to inequitable conduct based on withholding or mischaracterization of particular information, YOUR statement should include, but is not limited to, identification of all PERSONS alleged to have breached their duty of disclosure and/or candor with respect to any alleged withheld or mischaracterized information, a detailed explanation of why the allegedly withheld or mischaracterized information was material to patentability of the claims of the '415 PATENT, a detailed explanation of how the alleged withholding or mischaracterization of information was done with an intent to deceive by any of the PERSONS who allegedly breached their duty of disclosure and/or candor, and identification of all PERSONS most knowledgeable of and DOCUMENTS RELATING TO YOUR contention(s).

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 16

Centocor objects to this interrogatory as premature and untimely to the extent it seeks trial contentions or information within the scope of expert disclosures, testimony, or opinion governed by the Federal Rules of Civil Procedure. Centocor further objects to this interrogatory because it seeks information that is protected from discovery by reason of a privilege, work-product protection, and the protections afforded by Rule 26(b)(4)(B) of the Federal Rules of Civil Procedure.

Subject to the foregoing and the General Objections, and to the extent Centocor understands the terminology used by Genentech, Centocor directs Genentech to its First Amended Complaint for Declaratory Judgment and its Second Amended Complaint for Declaratory Judgment.

Centocor further states that the Cabilly II patent is unenforceable due to inequitable conduct because Genentech made material inconsistent statements to the PTO about U.S. Patent No. 4,366,216 to Axel ("the 216 patent"). For example, during prosecution of U.S. application no. 08/909,611 ("the 611 application"), which was a divisional of the U.S. application no. 07/205,419 ("the 419 application"), and contained the same specification as the 419 application, Genentech, through its patent agent Wendy Lee, submitted the declaration of John Ridgeway to the PTO. Mr. Ridgeway stated his view that the 611 application and the 216 patent taught a skilled molecular biologist how to prepare a modified CHO cell line expressing a monoclonal antibody in yields sufficient to conduct *in vivo* trials. (GNE-MED 094804-094805). In contrast, during the reexamination of the Cabilly II patent, Genentech, through its patent attorney Jeffery Kushan and/or patent agent Wendy Lee, told the PTO that the 216 patent was inapplicable to the Cabilly II patent. For example, Mr. Kushan told the PTO that "[t]he total absence in [the 216 patent] of any actual description of procedures for producing immunoglobulin molecules or immunologically active fragments through recombinant techniques renders the [216] patent irrelevant to the claims of the '415 patent claims.'" (GENE-CEN 003021). Mr. Kushan also remarked that the 216 patent "certainly does not demonstrate the predictability of producing multiple heterologous proteins that one intends to isolate in a single host cell. And [the 216 patent] cannot 'suggest the desirability of expressing immunoglobulins in mammalian host cells, and as intact (assembled) proteins' because there is literally no discussion of this in the [216] patent." (*Id.*). Ms. Lee was also involved on behalf of Genentech in the reexamination of the Cabilly II patent, as evidenced by, for example, her attendance of and participation in examiner interviews during the reexamination. Intent to deceive the PTO at least by Ms. Lee can be inferred because she knew about the Ridgeway declaration and characterized the disclosure of the 216 patent in materially different ways for concurrent prosecution of related applications. At the very least, she should have affirmatively identified the Ridgeway Declaration for the examiner of the 419 application instead of burying it in the middle of a 27 page IDS listing.

1 The Cabilly II patent is also unenforceable due to inequitable conduct because
 2 Genentech made certain statements about the Cabilly II invention to the PTO during
 3 interference no. 102,572 with U.S. Patent No. 4,816,397 (“the Boss patent”) when
 4 trying to claim priority (e.g., in connection with defining the subject matter invented)
 5 that were inconsistent with statements made by Genentech during reexamination of the
 6 Cabilly II patent when trying to define the invention for purposes of distinguishing the
 7 invention from the prior art. For example, during the interference, Genentech
 8 characterized the invention of the Count in an attempt to show priority over the Boss
 9 patent by stating (through lawyer Danny Huntington) that, prior to the Boss patent’s
 10 priority date, “Cabilly had transformed a single host cell with the DNA of at least the
 11 variable regions of the heavy and light chains of an Ig molecule, and had independently
 12 expressed the DNA of those chains to obtain separate molecules. As such, Cabilly had
 13 reduced the invention of Count 1 to practice. While not required by Count 1, Cabilly
 14 had also proceeded prior to the filing date of the Boss British priority document to
 15 produce reconstituted Ig antibodies and had demonstrated their antigen binding
 16 activity.” (GNE-MED-03185). Genentech further stated that “[t]he invention of Count
 17 1 does not require that an active antibody be produced directly.” (GNE-MED-03237).
 18 Genentech went on to state that “Boss contends that Count 1 requires that an active
 19 product, (i.e., an active immunoglobulin molecule consisting of 4 separate chains) be
 20 produced directly. However, this requirement is not an element of the Count.”
 21 (emphasis in original) (*Id.*). “Count 1 describes a process for producing an Ig molecule
 22 or an immunologically functional Ig fragment, comprising the steps of (i) transforming a
 23 single host cell with the DNA sequences for the heavy and light chains of an
 24 immunoglobulin molecule, and (ii) expressing both of the heavy and light chains as
 25 separate molecules in the single host cell. Nowhere in Count 1 does the language
 26 specify that these separate heavy and light chain molecules must associate to form
 27 active antibody molecules within the single transformed cell.” (*Id.*).

19 In contrast, during reexamination of the Cabilly II patent, Genentech, through
 20 attorney Jeffery Kushan and relying on the declaration of Dr. Steven McKnight, told the
 21 PTO that the claims of the Cabilly II patent “require three separate steps: (i) a host cell
 22 must be transformed with immunoglobulin heavy and light chain DNA sequences; (ii)
 23 the DNA sequences must be independently expressed (transcribed and translated) by the
 24 host cell to produce polypeptides; and (iii) the polypeptides must be assembled to form
 25 an immunoglobulin molecule or an immunologically functional immunoglobulin
 26 fragment (‘fragment’).” (GENE-CEN 002056-002057)

25 Thus, when trying to establish priority of the invention over the Boss patent,
 26 Genentech told the PTO that the Cabilly II invention did not require that an active
 27 antibody be produced and that the invention consisted of two steps: (1) transforming a
 28 host cell with heavy and light chain DNA, and (2) expressing both the heavy and light
 chains as separate molecules. But, in trying to distinguish its invention from the prior
 art, Genentech told the PTO during reexamination of the Cabilly II patent that the

1 claimed invention included three steps, including assembly of an immunoglobulin
2 molecule or an immunologically functional immunoglobulin fragment. Genentech failed
3 to inform the PTO during the reexamination of the Cabilly II patent of the prior
4 inconsistent statements it had made characterizing the invention during the Cabilly-Boss
5 interference. This information was material to the reexamination of the Cabilly II patent.
6 Intent to deceive the PTO can be inferred at least because Genentech knew or should
7 have know that positions it took during the interference were inconsistent with positions
8 it took during the reexamination in response to a PTO rejection and in attempting to
9 distinguish over the prior art.

10 Moreover, Genentech incorrectly told the PTO during reexamination that all of
11 the claims in the Cabilly II patent included the three steps discussed above, when, in
12 fact, claims 18 and 20 relate to transformed host cells and do not recite the independent
13 expression of heavy and light chain DNA sequences, or the assembly of an
14 immunoglobulin molecule or an immunologically functional immunoglobulin fragment.
15 This information was material to the reexamination of the Cabilly II patent. Intent to
16 deceive the PTO can be inferred at least because Genentech knew or should have know
17 that positions it took during the interference were inconsistent with positions it took
18 during the reexamination.

19 The Cabilly II patent is also unenforceable because Genentech withheld certain
20 data and experimental conditions related to *in vitro* reconstitution from the specification
21 of the Cabilly II patent. Dr. Wetzel, one of the inventors of the Cabilly II patent who
22 had a duty to disclose material information relating to the patentability of the claimed
23 invention, failed to disclose the experimental conditions for the data reported in the
24 Cabilly II patent, and for the experimental conditions that are disclosed in the Cabilly II
25 patent, failed to disclose the data actually generated under these conditions. This
26 information was material to the prosecution of the Cabilly II patent. Dr. Wetzel knew or
27 should have known that this information was material to the patentability of the claimed
28 invention. In fact, on at least two separate occasions during prosecution, Dr. Wetzel
submitted declarations on this subject matter but never disclosed the discrepancy
between his experiments and what is reported in the patent. Further, at some point Dr.
Wetzel became aware that there was a mistake in the data reported in the patent. Dr.
Wetzel could not deny that he knew about that mistake when submitting a declaration to
the PTO, in which he stated under penalty of perjury that the data was as reported in the
patent, and did not disclose the mistake. Intent to deceive the PTO can be inferred by his
failure to disclose the information to the PTO.

The Cabilly II patent is also unenforceable due to inequitable conduct because
Genentech failed to disclose material information to the PTO during prosecution of the
419 application. For example, during the prosecution of the 419 application,
Genentech's European equivalent of the 419 application was opposed and revoked in
Europe before the European Patent Office. In May 2001, the European Patent Technical
Board of Appeals ("EP decision") issued a decision in which it limited the Genentech

claims to antibodies made in E. coli cells, and found that the Cabilly specification did not enable the production of an antibody in a eukaryotic host cell, and that the claimed process was not enabled for mammalian cells in general. Genentech failed to cite the May 2001 EP decision to the PTO during the prosecution of the 419 application. A reasonable examiner would have wanted to know about the May 2001 EP decision as it was material to the patentability of the 419 application. Intent to deceive the PTO can be inferred from the fact that persons with a duty of candor to the PTO, acting on behalf of Genentech, knew about the EP decision and failed to cite it to the PTO.

Centocor is still in the process of conducting its inquiry into the facts and circumstances at issue in the present litigation. Discovery in this case is still ongoing, and the deposition of key witnesses, including Wendy Lee, have not yet been completed. Ms. Lee's deposition was noticed on January 27, 2010, and has only recently been scheduled for April 27, 2010. Centocor reserves the right to supplement this interrogatory response as the litigation progresses.

INTERROGATORY NO. 17

Provide a complete statement of each and every basis for YOUR contention(s) that the '415 PATENT is unenforceable due to prosecution laches, including but not limited to, all information that supports or rebuts YOUR contention(s) and identification of all PERSONS most knowledgeable of and DOCUMENTS RELATING TO YOUR contention(s).

RESPONSE TO INTERROGATORY NO. 17

Centocor objects to this interrogatory as premature and untimely to the extent it seeks trial contentions or information within the scope of expert disclosures, testimony, or opinion governed by the Federal Rules of Civil Procedure. Centocor further objects to this interrogatory because it seeks information that is protected from discovery by reason of a privilege, work-product protection, and the protections afforded by Rule 26(b)(4)(B) of the Federal Rules of Civil Procedure.

Subject to the foregoing and the General Objections, and to the extent Centocor understands the terminology used by Genentech, Centocor responds as follows: Centocor directs Genentech to its First Amended Complaint for Declaratory Judgment.

Centocor further responds that the '415 patent is unenforceable for prosecution laches because Genentech purposely delayed producing relevant, dispositive discovery in its interference with the Boss patent that unreasonably delayed the examination and issuance of the 415 patent. Dr. Cabilly testified that he had in possession at all times since leaving City of Hope a draft of priority application no. 07/205,419 dated February 25, 1983. Attorneys for Genentech asked Dr. Cabilly to produce documents that were in possession numerous times during the course of the interference, but he was never asked to produce the February 1983 draft, and only did so after termination

of the interference, and during a 146 Action filed by Genentech to appeal the interference decision. This resulted in an unreasonable delay in issuing the 415 patent that has prejudiced Centocor economically, and also in connection with its ability to gather evidence. The inventors, for example, on numerous occasions during their depositions, stated that they were unable to recall events from so long ago. The net result of timing with respect to the 415 patent issuance is effectively 35 years of patent term after filing. At this point, 25 years has already passes and the memories will not improve in there are further proceedings on the patent.

Centocor is still in the process of conducting its inquiry into the facts and circumstances at issue in the present litigation and reserves the right to supplement this interrogatory response as the litigation progresses.

Dated: April 21, 2010

AKIN GUMP STRAUSS HAUER &
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Attorneys for **Error! No text of
specified style in document.**

PROOF OF SERVICE

I, Angela Verrecchio, the undersigned, certify and declare that I am over the age of 18 years, employed in the County of Philadelphia, State of Pennsylvania, and am not a party to the above-titled case. My business address is: AKIN GUMP STRAUSS HAUER & FELD LLP, Two Commerce Square, 2001 Market St., Suite 4100, Philadelphia, PA 19103.

On April 21, 2010, I served a true and correct copy of the following document described as:

**CENTOCOR ORTHO BIOTECH, INC.'S SUPPLEMENTAL RESPONSES
TO GENENTECH'S INTERROGATORIES NOS. 16 & 17**

on the interested parties in this action as follows:

[X] By Email: I caused the document(s) to be sent to the person(s) at the email addresses set forth below.

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ddurie@durietangri.com

Executed April 21, 2010 in Philadelphia, Pennsylvania.

Angela Verrecchio

/s/ Angela Verrecchio

Name

Signature